

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 1-8 and 44-81, 84, 86, 87, 89 and 91-106 are pending after entry of the amendments set forth herein.

Claims 1-8 and 44-99 are subject to a restriction requirement. Claims 1-8 and 44-76 (Group I) were withdrawn from consideration by the Examiner in response to the provisional election by the Applicant of claims 77-93 (Group II).

Claims 77-93 were examined and rejected in the Office Action.

By the Amendment herein, claims 77, 78, 80, 81, 84, 86, 87, 89 and 91 are amended, claims 82, 83, 85, 88 and 90 are cancelled, and claims 94-106 are added. Support for the amendments to claim 77 are found in the specification on at least page 8 and on page 9, lines 1-13 and in original claims 16 and 34. The amendments to claims 78, 80, 84, 86, 87, 89 and 91 are of a clerical or typographical nature only. The amendment to claim 81 is supported in original (previously cancelled) claim 23. Support for newly added claims 94-106 is found in original claims 77-81 and 84 and throughout the specification.

The amendments herein are made to solely for the purpose of further defining the invention.

No new matter has been added.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

**Election/Restriction**

The claims have been restricted as follows:

Group I, claims 1-8 and 44-76 – drawn to a method for preserving organs.

Group II, claims 77-93 – drawn to a pharmaceutical composition.

Applicant affirms the provisional elected to prosecute Group II, however, it does so with traverse in view of the fact that a lack of unity objection was not raised with respect to the collective grouping of the claims of Groups I and II by the International Searching Authority or the Preliminary Examination Authority during the International Phase of the PCT Application to which the subject application claims priority under 35 U.S.C. 371. In this regard, the PCT Handbook, at section 33.35 entitled "Unity of Invention in the National Phase", states "[t]he PCT Contracting States have agreed to follow the practice under the Patent Cooperation Treaty on unity of invention...therefore, a designated Office ought not to

raise an objection as to a lack of unity when the International Searching and/or Preliminary Examining Authority has found that the claims comply with the requirement for unity of invention (Rule 13 PCT)."

In view of the above, the Applicant respectfully requests reconsideration and withdrawal of the restriction requirement.

### **Claim Objections**

Claims 80 and 81 were objected to because the term "mepivacaine" was misspelled. The misspelling has been corrected in amended claim 80 and deleted in amended claim 81.

### **Claim Rejections Under 35 U.S.C. §112**

Claim 81 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite as the claim was duplicative of claim 80. Claim 81 has been amended to depend from claim 80 and to further define Class 1B antiarrhythmic agents.

### **Claim Rejections Under 35 U.S.C. §102**

Claims 77, 78, 80-83 and 90 were rejected under 35 U.S.C. §102(b) as being anticipated by each of the following references: Antropoli (WO 98/37886), Homeister et al., Garrett et al. and Jayawant et al.

These rejections have been made moot with respect to claims 82, 83 and 90 as these claims have been cancelled herein. With respect to claims 77, 78, 80 and 81 as amended, neither of the cited references alone or in combination disclose, suggest or teach a composition comprising a pharmaceutically acceptable carrier; a compound chosen from a potassium channel opener, a potassium channel, a potassium channel agonist and an adenosine receptor agonist; and a local anesthetic; wherein the compound and the anesthetic are present in the composition in amounts sufficient to arrest the heart.

Accordingly, reconsideration and withdrawal of the pending rejections are requested.

### **Claim Rejections Under 35 U.S.C. §103**

Claims 77, 78 and 80-89 were rejected under 35 U.S.C. §103(a) as being unpatentable over Jayawant et al.

These rejections have been made moot with respect to claims 82, 83, 85, 88 and 89 as these claims have been cancelled herein. With respect to claims 77, 78, 80, 81, 84, 86 and 87 as amended,

Jayawant et al. alone or in combination with Raymond (U.S. Pat. No. 5,693,462) does not suggest or teach a composition comprising a pharmaceutically acceptable carrier; a compound chosen from a potassium channel opener, a potassium channel, a potassium channel agonist and an adenosine receptor agonist; and a local anesthetic; wherein the compound and the anesthetic are present in the composition in amounts sufficient to arrest the heart.

Accordingly, reconsideration and withdrawal of the pending rejection are requested.

Claims 77, 78, 80-83 and 90-93 were rejected under 35 U.S.C. §103(a) as being unpatentable over Garratt et al. in view of Glasser et al. (U.S. Pat. No. 5,256,770).

These rejections have been made moot with respect to claims 82, 83 and 90 as these claims have been cancelled herein. With respect to claims 77, 78, 80, 81 and 91 as amended and to claims 92 and 93, Garratt et al. alone or in combination with Glasser et al. does not suggest or teach a composition comprising a pharmaceutically acceptable carrier; a compound chosen from a potassium channel opener, a potassium channel, a potassium channel agonist and an adenosine receptor agonist; and a local anesthetic; wherein the compound and the anesthetic are present in the composition in amounts sufficient to arrest the heart.

Accordingly, reconsideration and withdrawal of the pending rejection are requested.

Claims 77-83 and 93 were rejected under 35 U.S.C. §103(a) as being unpatentable over Garratt et al. or Homeister et al.

These rejections have been made moot with respect to claims 82 and 83 as these claims have been cancelled herein. With respect to claims 77, 78, 80 and 81 as amended and to claim 93, neither Garratt et al. nor Homeister et al. nor their combination suggest or teach a composition comprising a pharmaceutically acceptable carrier; a compound chosen from a potassium channel opener, a potassium channel, a potassium channel agonist and an adenosine receptor agonist; and a local anesthetic; wherein the compound and the anesthetic are present in the composition in amounts sufficient to arrest the heart.

Accordingly, reconsideration and withdrawal of the pending rejection are requested.

#### **Newly Added Claims**

None of the cited references alone or in combination disclose, suggest or teach a composition comprising a pharmaceutically acceptable carrier; a compound chosen from a potassium channel opener,

a potassium channel, a potassium channel agonist and an adenosine receptor agonist; and a local anesthetic; wherein the compound and the anesthetic are present in the composition in amounts sufficient to protect or preserve an organ.

Accordingly, newly added claims 94-106 are patentable over the prior art, and Applicants respectfully request allowance of such claims.

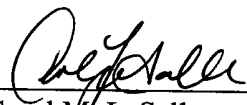
**Conclusion**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number FREE-001.

Respectfully submitted,  
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Date: 9/9/03

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